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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,284	11/19/1999	RONALD VOGELS	4231US	8464

7590 11/26/2002

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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/26/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/444,284Applicant(s)
Vogels et al.Examiner
Shin-Lin ChenArt Unit
1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Oct 29, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Oct 29, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☒ Applicant's reply ^{would} ~~has~~ overcome the following rejection(s) ^{when amendment is entered}:
Double patenting, 112 second paragraph, 102(b), and 103(a) rejections.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
Applicants argue that the claims are amended to read on recombinant adenovirus and the specification provides support for the claimed recombinant adenovirus (amendment, p. 8). This is not found persuasive because of the

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 2, 19, 21, 25, 28-32, 37-40, 42, and 44-59

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

Art Unit: 1633

DETAILED ACTION

Continued from Advisory Action:

record. The claims encompass various types and species of adenovirus that has at least a tissue tropism for smooth muscle cells or with reduced tissue tropism for liver cells, and the tropism could be provided by a adenovirus capsid comprising protein **fragments** from at least two different adenoviruses. The scope of the claim includes nucleic acid vectors or viruses encoding a genus of numerous structural variants of the tropism-determining protein of various adenovirus, such as fiber protein of adenovirus, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification fails to provide the structural features of a tropism-determining protein from different adenoviruses. Structural features that could distinguish compounds in the genus from others in the polypeptide class are missing from the disclosure. No common structural attributes identify the members of the genus. Therefore, the fiber protein chimera as disclosed in the present application is insufficient to describe the genus.

Applicants argue that the claims are amended to read on recombinant adenoviruses and the specification provides support for the claimed adenoviruses and cells (amendment, page 8-9). This is not found persuasive because of reasons of record. The specification fails to provide adequate guidance and evidence for how to alter the tropism-determining protein of an adenovirus such that the mutated protein or chimeric protein fragments from at least two

Art Unit: 1633

different viruses could provide tissue tropism for smooth muscle cells, increased tropism for endothelial cells or provide reduced tissue tropism for liver cells *in vitro* or *in vivo*. The claims encompass various adenoviruses derived from various organisms. Protein function was not predictable from mere amino acid sequence at the time of the invention. It was unpredictable at the time of the invention whether various altered tropism-determining proteins, chimeric proteins having protein fragments from at least two different adenoviruses, such as fragments of virus capsid proteins, could provide a tissue tropism for SMC, increased tropism for endothelial cells, or reduced tissue tropism for liver cells *in vitro* or *in vivo*. Further, the specification fails to provide adequate guidance and evidence for the use of the claimed recombinant adenoviruses for *in vivo* gene therapy and the correlation between the adenoviruses encoding a protein of interest and a particular disease in a patient. The specification also fails to provide adequate guidance and evidence for how to deliver the recombinant adenoviruses expressing any gene product under the control of any promoter to a patient and sufficient gene products could be produced at the targeted site so as to provide therapeutic effects for a particular disease or disorder in said patient *in vivo*. Thus, the claims remain rejected under 35 U.S.C. 112 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

Art Unit: 1633

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'shchen', located below the printed name.